

the reservoir portion or portions comprising a releasable dose of the medicament in a fluid form, with a viscosity below 800 mPas at body temperature, such that on mastication, the masticable portion is ruptured and the unit dose of the medicament is released in a short space of time from the reservoir portion into the oral cavity.

14. (new) An oral formulation for a medicament comprising:

a solid masticable portion and one or more reservoir portions encompassed by said solid masticable portion;

the solid masticable portion having a Young's modulus of 0.01-5Mpa, and compressive strength in the range 10-10,000 mJ, comprising at least 50% by weight of the total solid content selected from the group consisting of polysaccharides and hydrogenated polysaccharides, a viscoelastic polymer additive in an amount of not more than 50% by weight, optionally a mucoadhesive additive in an amount of not more than 20% by weight, optionally flavourings and colourings in an amount of not more than 30% by weight, and optionally preservatives and antioxidants in an amount of not more than 5% by volume,

the reservoir portion or portions comprising a releasable dose of the medicament in a fluid form, with a viscosity below 800 mPas at body temperature,

such that on mastication, the masticable portion is ruptured and the unit dose of the medicament is released in a short space of time from the reservoir portion into the oral cavity.

Remarks

After entry of this amendment, claims 1-14 are pending in the present application. Claim 1 (amended) and new claims 12 and 13 are presented with amendments relating to the definition of "edible" and the further clarification of the composition of the masticable portion. Newly presented claim 14 contains a further listing of the ingredients in the masticable portion set forth on page 5, line 6 through page 6, line 8. Support for "edible and digestible" is found at page 3, lines 15-16, and support for claim 14 additive amounts and the "a majority by weight of hydrogenated polysaccharides" at page 5, line 7 in combination with page 6, lines 3-5 and the Examples A-Q.

No new matter is felt to arise by these amendments.

II. **Claim Rejections Under 35 U.S.C. § 103(a)**

The Examiner rejects claims prior pending claims 1-11 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 4,428,927 to Ebert et al ("Ebert"). This rejection is respectfully traversed.

The present application is directed to oral formulations set forth in amended claim 1 that include a solid masticable portion consisting of an edible and digestible material, comprising a majority by weight of hydrogenated polysaccharides material. Newly presented independent claims 12 and 13 set forth the edible and digestible material and the majority polysaccharide features separately. Each independent claim specifies the desired balance of stiffness and compressive strength properties conducive to promoting mastication. New claim 14 further specifies the ingredients of the masticable portion. The present invention also is directed to methods of treatment with such formulations.

Ebert demonstrates no appreciation for these important features. Quite the contrary, Ebert discloses chewable formulations that include 1-75% of an insoluble masticatory substance. Col. 2, lines 31-41. Such insoluble materials are essential to Ebert in solving the problem of capsules that generally dissolve "rapidly in the mouth, thereby leaving little or no residue for further chewing." Col. 1, lines 41-45. As such, Ebert teaches that a chewable product should "leave a chewable, insoluble residue in the mouth and this residue should not change significantly in size upon continued chewing; at all times, the insoluble residue should retain a generally normal chewing texture or consistency." Col. 1, lines 45-51.

This invention stands patentably distinct from Ebert by recognizing the need for materials which are both "edible and digestible" which may be preferably achieved using a "majority by weight of hydrogenated polysaccharides" thereby achieving a desirable composition with "mechanical properties conducive to promoting mastication, namely stiffness as measured by Young's modulus of 0.01-5Mpa, and compressive strength in the range 10-10,000 mJ. There is no recognition in the prior art of the importance of this combination of properties in an edible, digestible formulation.

Applicants contend that the amended claims are not *prima facie* obvious in view of Ebert. The Board of Patent Appeals and Interferences has stated that "to establish a *prima facie* case of obviousness, it is necessary for the examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references

in the proposed manner to arrive at the claimed invention." Ex parte Levingood, 28 U.S.P.Q.2d 1300, 1301 (BOPAI 1993). Not only must there be evidence of motivation, but also, the skilled worker must have an expectation that the modified teachings would be successful. Ebert fails to meet these requirements.

A skilled worker would have to be motivated to modify Ebert's formulation from one containing an insoluble material to one that consists of an edible and digestible material. It is well known that digestion requires at least partially soluble materials, materials that are capable of being assimilated into the body. As such, a skilled worker would not be motivated to modify Ebert's formulations to include edible and digestible materials because Ebert teaches away from using formulations consisting of digestible products by stating that chewables should leave an insoluble residue in the mouth. Given this teaching, a skilled worker would not expect formulations consisting of digestible materials to be successful.

Further, Ebert has no appreciation of the desirability of the balance of mechanical properties of stiffness and compressive strength set out in the Applicant's invention. As a result, Applicants respectfully request withdrawal of this rejection.

Favorable action in the form of a Notice of Allowance Issue is sincerely felt to be appropriate.

Should the Examiner have any questions or comments regarding this amendment or the application in general, the Examiner is invited to call the undersigned at (860) 715-4271.

A petition for a three-month extension of time is included herewith along with the RCE request form; as such, the Commissioner is hereby authorized to charge the three month extension of time fee, and any other fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445.

Respectfully submitted,



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